Responses and Comments

The applicant would reiterate or supplement the prior comments in this writing. The test is for a protein that binds 25-hydroxy vitamin D. That is the function of the test. It was developed to determine salt sensitivity, but could be used for any purpose wherein binding of 25-hyroxy vitamin D by a protein is at issue. The claim has been rewritten to more clearly indicate that. Should such binding activity have any other significance, the different significance would not alter the fact that binding 25-hydorxy vitamin D by a protein is under investigation.

Both independent method and kit claims have been rewritten and the prior independent claims cancelled. Expanding on the arguments of the original Response filed January 21, 2009, the two samples are used because when the unlabeled 25-hydroxy vitamin D binds to the protein and is present only in one of the samples or sample sets, the sample has less, if any, protein capable of binding available to bind to the labeled 25-hydroxy vitamin D. The sample lacking the unlabeled 25-hydroxy vitamin D would then show greater binding with the labeled 25-hydroxy vitamin D than the sample with the unlabeled, since all binding protein would have to interact with the labeled 25-hyrdroxy vitamin D.

The examiner has questions use of terminology, namely, that "vitamin D" and sometimes "vitamin D_3" are seemingly interchangeably and it is unclear what is desired." It is believed the claim 12 better indicates the specific use of the term, the specific reagents being used in the assay (present in the kit) being the D_3.

The discussion relating to the references as provided on January 21 are deemed appropriate and is not reiterated herein.

Regarding the kit claim, kits with reagents, including proteins for determining metabolite amounts do sometimes contain charcoal to precipitate an unbound metabolite. However, the charcoal without an antibody is appropriate in this kit, since the protein is coming from the urine, and no antigen-antibody reaction is being undertaken. The novelty lies in that this is a binding test, and not a test for the protein as such. Hence, no protein in the form of antibodies or proteins

that are not antibodies are part of the kits. There is no need to identify amount of any protein, but only binding power, so antibodies usually used in tests are not needed.

If any further discussion would facilitate prosecution, the Examiner is invited to call the undersigned at 703 425 8405.

Respectfully submitted,

Glenna Hendricks, Reg. 32,535